UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,663	02/06/2002	Chuan Li		9010

7590 04/21/2006

Chuan Li
Apt. 158
7908 Avenida Navidad
San Diego, CA 92122

EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,663	LI, CHUAN	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,24-31 and 33-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,24,25,29-31 and 33-38* is/are rejected.

7)☒ Claim(s) *26-28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 21 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Mizutani (US Patent no. 3,880,814).

Mizutani teaches of a composition or sample solution comprising at least three polypeptides of different known size and of different known amounts. The sample solution comprises 15 mg of the polypeptide conalbumin having a molecular weight or size of 87,000, 4 mg of ovalbumin having a molecular weight or size of 46,000, and 7 mg of lysozyme having a molecular weight or size of 14,600. See lines 6-13 in column 4 of Mizutani. The three polypeptides in the composition taught by Mizutani are the same polypeptides as taught in Example 1 on page 11 of the instant specification, and therefore, the size of the polypeptides disclosed by Mizutani would inherently cover a range that is separable by polyacrylamide gel electrophoresis, and the amounts of the polypeptides taught by Mizutani would inherently cover a range that is detectable by a given protein detection assay.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 25, 29-31 and 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizutani. For a teaching of Mizutani, see previous paragraphs in this Office action.

Mizutani fails to teach that the polypeptides conalbumin, ovalbumin and lysozyme are present within a kit, and fail to teach that in preparing the solution containing the three polypeptides, the amounts of the polypeptides are estimated using a detection assay with different amounts of a standard protein such as BSA. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the polypeptides in the solution taught by Mizutani into a kit so as to have all of the polypeptides present in a single container in the correct amount in order to facilitate the quick and easy performance of the method taught by Mizutani. It also would have been obvious to one of ordinary skill in the art at the time of the instant invention to estimate the recited amounts of the polypeptides taught by Mizutani (15 mg conalbumin, 4 mg ovalbumin and 7 mg lysozyme) using a detection assay with different amounts of a standard protein such as BSA since it is common knowledge in the art of protein assays to use a standard such as BSA in different known amounts in order to determine the amounts of polypeptides in an unknown sample, and to express the amounts of the

polypeptides as equivalent amounts of the standard protein, as evidenced by Applicant's own admission in the response received on February 15, 2006.

6. Claims 26-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims since none of the prior art of record teaches or fairly suggests a method for estimating both the size and amount of a polypeptide in a protein sample by electrophoresing simultaneously in separate lanes on a gel the protein sample and a protein standard containing at least three different polypeptides therein having different sizes from one another and being present in different amounts from one another, wherein the amounts of the polypeptides in the standard are expressed as an equivalent amount of a standard protein, detecting the polypeptides on the gel with a detection assay to obtain the relative positions and detection intensities of the polypeptides, comparing the relative positions of the polypeptides of the protein standard with the relative position of the polypeptide in the protein sample to estimate its size, and comparing the relative detecting intensity of the polypeptides of the protein standard with the relative detecting intensity of the polypeptide in the protein sample to estimate its amount.

7. Applicant's arguments with respect to claims 21, 24-31 and 33-38 have been considered but are moot in view of the new ground(s) of rejection.

The previous rejection of the claims under 35 USC 112, first and second paragraphs made in the last Office action mailed on November 16, 2005 are withdrawn in view of Applicant's amendments to the specification and claims. However, the amendments to the specification will not be entered at the present time since they are not in the correct format. In

order for the amendments to the specification to be entered, Applicant must repeat the entire paragraph in which the insertions are made. In particular, the entire paragraphs in Examples 1, 2 and 3 of the specification must be repeated with the amendments inserted therein.

This Office action is not being made final because of the new grounds of rejection.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

April 6, 2006

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted] 1700